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## Health Reform Monitor

Welsh 2013 deemed consent legislation falls short of expectations<sup>☆</sup>Jordan Alexander Parsons<sup>\*</sup>

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## ABSTRACT

Wales, in 2013, was the first country in the United Kingdom to pass legislation introducing presumed (or deemed) consent for organ donation, and remains the only one. It was introduced in an attempt to increase the number of life-saving transplants taking place in the UK, in a move that policy makers hoped would mirror Spain's success. More recently, pressure has been mounting for England to follow suit, with a public consultation currently in progress. However, the Welsh system has been far from a success, raising the question of why campaigners are so adamant that it should be replicated. Before the Welsh Government introduced the Human Transplantation (Wales) Act there had been no strong evidence to suggest it would make a difference, with countries boasting both high organ donation rates and presumed consent legislation demonstrating no clear causal relationship between the two facts. In addition, a recent report evaluating the Act has highlighted its failure to improve donation rates, and has even presented some potentially concerning statistics that may suggest a negative impact. This paper first considers presumed consent in other countries – Spain and Brazil – before illustrating the underwhelming progression of Wales' new system and the need to look to other options.

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## 1. Policy introduction

One of the most commonly proposed responses to the acute organ shortage which exists in numerous countries is the introduction of a system of presumed consent, whereby, in the absence of a formal objection, the individual is taken as having consented to donation. The Human Transplantation (Wales) Act 2013 marked the first example of a system of presumed consent – or “deemed consent” in the Act's wording – in the UK. Hailed by First Minister, Carwyn Jones, as ‘arguably the most significant piece of legislation’ to come from the National Assembly for Wales since the devolution of full lawmaking powers in 2011, hopes were high for organ donation in Wales following the change. Of particular interest is the fact that the law was passed after the Department of Health's Organ Donation Taskforce, which the Welsh Assembly Government was involved with, made no such suggestion [1]. Now, less than 3 years into the new Welsh system, pressure is mounting on Westminster to introduce a similar system in England. A Department of Health public consultation is currently in progress to ascertain whether presumed consent would result in overwhelming public support.

As was the case with Wales, it is hoped that presumed consent will improve donor rates in England. Campaigning in England has continued throughout the initial period of the Welsh law, despite the distinct lack of improvement in Wales' donation and transplant statistics.

Under the Welsh system, the deceased is deemed to have consented to donation unless (1) a decision as to donation by the deceased is in force, (2) the deceased had appointed a person or persons to make the decision on their behalf, or (3) a relative of friend of long standing objects on the basis of views held by the deceased and it is reasonable to assume the objection is accurate [2]. It is down to the medical team to determine whether a relative's objection is their own, or one based on the views of the deceased. Unsurprisingly, doctors have not shown willing to challenge these objections, despite their legal right to; they consider it inappropriate to go against the wishes of the family.

This policy is often viewed as infringing on autonomy, a cornerstone of the medical profession in the Western world. However, policymakers argue that individuals still have the ability to exercise their autonomy, as objecting to donation is still an option. Further, surveys have indicated support of up to 90% for organ donation in the UK, so presumed consent is seen as encouraging those who support it in principle to support it in practice.

It is important to remember that the family would have been consulted prior to the change in legislation. Whilst the way in which they are asked has altered, with the concept of deemed consent

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acting as a nudge, the simple fact that the family are consulted has not changed.

## 2. Presumed consent in practice

As Wales hoped to emulate the success of other countries with presumed consent systems, it is prudent to consider some.

In practice, there are two different approaches to presumed consent; soft opt-out and hard opt-out. The former involves the family in decisions, whereas the latter strictly permits the harvesting of organs in the absence of an official objection from the deceased. Both have been introduced outside of the UK, with mixed results. New countries are adopting them from time to time, most recently the Netherlands [3].

### 2.1. Spain

Frequently touted as a prime example of the success presumed consent can bring, Spain introduced a soft opt out system in 1979. The country also has the best organ donation rates in Europe, closely followed by Croatia. However, something often neglected when Spain is being used as an example is the fact that it was not until 10 years after the change to the law that donor rates began to improve [4]. It would be wrong, then, to claim that Spanish success is a result of the change in law. What has led to success in Spain is investment, with the introduction of better infrastructure and, perhaps most importantly, dedicated staff to identify potential donors early on and build relationships with the family ahead of the time at which a decision will need to be made. This time spent with families is vital to building trust, as is the inclusion of faith leaders where appropriate, helping to overcome the problems that can arise from religious families being asked to donate and not being entirely clear on their faith's stance on organ donation – particularly important in multi-faith and multi-ethnic countries. The Spanish media also appears more invested in organ donation which is hugely influential in changing public opinion gradually and successfully; this is something that is starting to improve in the UK, with documentaries and media appearances presenting the stories of patients on the transplant list, but only recently has this sort of coverage grown.

We cannot entirely rule out the change to the law having some effect, but this is unlikely, and it certainly cannot be claimed to be wholly responsible. Given the changes to the way donation and transplantation are handled in Spanish hospitals, the legislation itself proves somewhat pointless. As it is a system of soft opt out, the family are still approached, and are still able to stop donation going ahead. Even though the law requires a reasonable belief on the part of the doctors that the relatives' objection is based on the views of the deceased, the reality is that doctors do not go ahead with the harvesting of organs where the family oppose it. This is understandable given it would be hard to disregard a very emotional family member insisting donation should not take place, and it is viewed as unreasonable to expect doctors to do so. Nonetheless, this demonstrates how the law itself has no clear effect, whereas the procedural changes in the medical setting are responsible for facilitating higher donation rates.

### 2.2. Brazil

In 1997, Brazil passed presumed consent legislation [5]. The system introduced was a rare example of hard opt-out, whereby the family are not consulted; in the absence of a documented objection from the deceased, which would be noted on that individual's identity card or driver's license, donation would go ahead. Understandably, there was resistance. Critics claimed that in practice, this law was making donation compulsory for a significant propor-

tion of the population, as many Brazilians would not have access to information regarding how to register their objection.

Another concern was with the potential for the law to make a difference; it was not expected to have a significant impact on the number of transplantable organs available. This was down to the lack of necessary infrastructure to successfully execute transplants. For a transplant to take place, organs need to be properly collected from the deceased, a potential recipient notified, and the two brought together quickly enough to give the transplant a high chance of success. Without appropriate processes in place, legislation to permit the use of organs becomes irrelevant. In reality, Brazil did not urgently need an increase in available organs, as prior to the law there was a surplus of organs due to the inefficiency of the system.

The law was abolished the following year, just 20 months after it was passed [6]. Continued criticism from medical organisations, as well as doctors being uncomfortable acting without family consent, contributed to the downfall of the system. In addition, further structural reasons failed to increase the number of transplants taking place. This ran alongside fear among the population, typified by mistrust of the government and accusations of body snatching.

Brazil's experience demonstrates two findings; firstly, that hard opt out, regardless of its effect on statistics, is too unpopular to be maintained; and secondly, similarly to Spain, legislative change alone does not make a difference.

## 3. Welsh deemed consent over time

Despite having been in practice for less than 3 years, assessments of the Welsh deemed consent system are plentiful. A look at organ donation through the history of the legislative change (Fig. 1) shows that failure was anticipated by some members of the public and academics, yet went ahead regardless.

### 3.1. Pre-legislation

The legislation was intended to boost the number of donors in Wales by 25%, reducing the number of deaths of those on the transplant waiting list. Welsh Assembly Members (AMs) were heavily in favour, with 43 of the 53 who voted backing the bill. Then Cabinet Secretary for Health and Social Services, Mark Drakeford, declared it a 'progressive policy' for a 'progressive nation' [7]. Perhaps not as progressive as Drakeford believed, seeing as similar legislation had been in place for decades in other countries, but it is clear that expectations were high for this system in the Welsh context.

Not all AMs were in agreement. Whilst the Welsh Government's health committee agreed on the progression of the bill, concerns were raised over the role of the family and the extent to which families would be involved in decisions. They called for clarity going forward, highlighting how important it is for medical staff dealing with difficult situations in the future [8].

Worries were expressed by various religious communities, with Joyce Robbins of campaign group Patient Concern claiming the absence of an objection equating to consent to be a lie; it cannot be assumed that everyone would be aware of the need to object, or would be able to do so. The Christian Medical Fellowship's Dr Peter Saunders was equally concerned, explaining that whilst Christian principles strongly associate with organ donation, this should be as a gift; the taking of organs, he argued, is unethical [9]. There were also suggestions that public fear of the system would ensue. These objections were based not on the incompatibility of organ donation with religious beliefs, but the fact the system would remove the altruistic nature that had previously been a hallmark of the act of donation.

<i>Pre-legislation</i>	<ul style="list-style-type: none"> <li>- Welsh Assembly Members back Human Transplantation (Wales) Bill, with 43/53 in favour</li> <li>- Some AMs call for greater clarity over the role of the family going forward, stating the importance of this to medical staff dealing with difficult situations</li> <li>- Worries from religious communities that deemed consent goes against important altruistic nature of organ donation</li> <li>- Pragmatic objections from those who felt the system would not work, and that it would result in public fear of the system</li> </ul>
<i>Short Term</i>	<ul style="list-style-type: none"> <li>- New system deemed 'promising' by the media</li> <li>- Welsh Government claims dozens of lives already saved by deemed consent</li> <li>- No sudden spike in the number of donations</li> </ul>
<i>Medium Term</i>	<ul style="list-style-type: none"> <li>- Welsh Government's 'Impact Evaluation Report' (Nov. 2017) shows no improvement in donation statistics</li> <li>- Downward trend in number of families approached</li> <li>- Positive media reports based on short series of data</li> <li>- Enthusiasm for policy appears to wane</li> </ul>

**Fig. 1.** Welsh deemed consent over time.

Others objected on the grounds that they simply did not see it working. Robby Berman of the Halachic Organ Donation Society stated that he would be in favour of opt out if it worked, but felt the focus should be on 'education not legislation' [10]. Berman's view clearly fitted with the reality of the Spanish experience, and more recently has been somewhat verified by released data.

### 3.2. Short term

Less than a year after the Act came into force, the new system was deemed 'promising' [11]. Just 6 months in, the Welsh Government claimed dozens of lives had already been saved as a result of the system. More than half of the 60 organs transplanted in this period were said to have come from those whose consent was "deemed". This interpretation is not reliable, as these relatives would have been asked about donation under the previous opt in system; it is perfectly reasonable to assume they would have consented in the absence of deemed consent. In addition, the number of donations taking place in this time was no greater than would have been expected based on data from before the legislative change.

### 3.3. Medium term

The most significant analysis of the new system is the Impact Evaluation Report, released by the Welsh Government in November 2017 [12]. Whilst focussing on the positives, such as increased understanding among medical staff, the report cannot escape the donation statistics, which clearly show no improvement. Covering the period from January 2010 or January 2011 to September 2017, all donation data show no change since the legislation's introduction. The 21-month period before the Act came into effect saw 101 deceased donors, whereas the same period after showed 104; an increase, but one that can be properly attributed to expected annual fluctuation.

Data for the number of families approached are potentially concerning. There is a clear downward trend in the number of families approached since the Act came into force, with the number per quarter remaining steadily between 30 and 50 in the years 2010–2014, before moving towards the 20–40 range in 2015. Of course, with the data showing the number approached rather than a percentage of potential donors approached, it is possible that there were less potential donors in this period. This conclusion is, unsurprisingly, supported by the Health Secretary for Wales, Vaughan Gething [13]. With only a 2-year period to observe, the data are to be taken with a pinch of salt, but if this trend continues then the reason(s) will need to be explored.

The media has reported on the increased percentage of families giving consent for donation [13]. From a low of 44.4% at the end of 2014 to the highest since the beginning of 2011 at 64.5% in Q2 2017 (the most recently reported data). Though if one looks at the full series from January 2011, a steady drop throughout 2014 is observed, before a steady rise from the beginning of 2015. This rise continued at a steady rate following the Act coming into force in December 2015, with the 64.5% being negligibly higher than the percentage in Q1 2011. What initially seems to be a drastic improvement is in fact a recovery from an unfortunately poor 2014.

Perhaps in an attempt to detract from the less than encouraging donation data, the report highlights increased support for the new system among healthcare workers. This is important information as frontline staff have insights that objective donation statistics do not illustrate. Though if the drop in the number of relatives approached is not a result of fewer potential donors, it will be necessary to consider why NHS staff are more supportive now; increased support would suggest increased approaching of relatives.

Following the release of this report, enthusiasm for the policy appears to have waned. Llio Dudley, a transplant recipient, explains: 'After looking at the statistics and speaking to people all over Wales, there doesn't seem to be much difference at all since the law came into force. That's disappointed me – I hoped there would have been an improvement in two years' [14].

## 4. Conclusion

Deemed consent has only been in force for 2 years in Wales. Whilst not conclusive, it is useful to analyse initial data. The data strongly suggest that Wales' deemed consent system has made no difference, failing to improve the number of donations and thus transplants. The target set by the UK Strategy 'Taking Organ Transplantation to 2020' [15], to reach a consent rate of 80% by 2020, seems unrealistic in Wales. NHS Blood and Transplant have noted that family refusals are the biggest obstacle [16]. That being the case, a system that continues to seek the permission of the family is evidently going to require more than legislation alone to be successful; the focus needs to be on getting people talking so that people are aware of the wishes of their family and friends with regards to organ donation, for this knowledge may well be the best way to overcome family refusals. Where increased awareness and family communication is successful the legislative change is, at best, of secondary importance.

In an attempt to improve family consent rates, renewed efforts are being made to encourage people to discuss their wishes with loved ones, in the hope that awareness of the deceased's wish to donate will result in the family honouring it. Working to improve

awareness and discussion is set to be the primary focus moving forward, perhaps fuelled by the realisation that the legislation alone has not made the tangible difference it was implemented to make; increased awareness would have been more suitable before legislative change, as in practice the new system acts only as an indicator of the Welsh Government's commitment to organ donation rather than a cause of change. With the aim being to alter the public psyche regarding organ donation, it seems only prudent to focus on young people; adding it to the national curriculum will go some way to normalising donation in the next generation. Steps in this direction are being made, with the introduction of organ donation education packs for schools and greater NHSBT social media activity.

We must also consider what may happen if the Welsh Government in the near future considers the new system a failure. If informed consent were to return in Wales, things may be worse than ever; the failed attempt at deemed consent may damage public perception of the organ donation endeavour. As such, it is vital the necessary changes to complement the new legislation are introduced.

With low organ donation rates proving problematic across the globe, one would expect all eyes to be on Wales as the latest example. However, despite a lack of evidence that deemed consent is having a positive effect on donor rates, support for the policy in England is still strong. Outside of the UK, the Netherlands announced a move to the system in February this year. The example of Wales appears not to have been heeded.

### Conflict of interest statement

None.

### Acknowledgement

None.

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